NOV 2 4 2004

510(k) Summary

K042133

as required by 807.92

1. Company Identification

Konica Minolta Medical & Graphic Inc.
2970 Ishikawa-cho, Hachioji-shi, Tokyo, 192-8505 Japan
Tel : 011-81-426-60-9607
Fax : 011-81-426-60-9588

2. Official Correspondent

Koji Kubo (Mr.)
Assistant Manager
Technical Support Group

3. Date of Submission

August 6, 2004

4. Establishment Registration No.

3003769120

5. Device Trade name

Dry Laser Imager, DRYPRO Model 793

6. Common Name

Medical Image Hardcopy Device

7. Classification

Medical image hardcopy device was reviewed by the Radiology Panel and classified in Class II per 21 CFR 892. 2040.

8. Product Code

90 LMC

9. Predicate Device

The Dry Laser Imager, DRYPRO Model 793 is substantially equivalent to DRYVIEW 8900 manufactured by Eastman Kodak Company, 510(k) No.: K033821.

Comparison of the principal characteristics of the two devices which are pertinent to Specification performance is attached below.

10. Description of Device

The Dry Laser Imager, DRYPRO Model 793 is a Laser Imager to acquire images from diagnostic equipment such as CT, MRI, DSA or Full Field Digital Mammography System and print them on medical dry-film.

The device consists of film supplying unit and film transferring unit and exposing unit and heat-developing unit and operating unit and power supplying unit and main control unit.

This product employs semiconductor laser for laser scanning, but it complies with the Federal Performance Standard 21 CFR Part 1040.10.

11. Intended Use

The Dry Laser Imager, DRYPRO Model 793 is intended to be used to acquire of images from diagnostic equipment such as CT, MRI, DSA or Full Field Digital Mammography System and print the images on medical dry-film.

The devices are intended to be used by trained medical personnel in a clinic or hospital environment.

12. Compliance Standard

UL60601-1 (expected to be approved by the end of October, 2004), IEC60601-1, IEC60601-1-2, IEC60825, 21 CFR 1040.10, DICOM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Konica Minolta Medical & Graphics, Inc.
% Mr. Shinichi Yamanaka
Progress Section
Cosmos Corporation
319 Akeno, Obata-cho
Watarai-gun, Mie-ken 519-0501
JAPAN

Re: K042133
Trade/Device Name: Dry Laser Imager, DRYPRO Model 793
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: 90 LMC
Dated: October 28, 2004
Received: October 29, 2004

Dear Mr. Yamanaka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) :

Device Name : Dry Laser Imager, DRYPRO Model 793

Indications For Use:

The Dry Laser Imager, DRYPRO Model 793 is intended to be used to acquire images from diagnostic equipment such as CT, MRI, DSA or FDA-approved Full Field Digital Mammography System and print the images on medical dry-film.

The devices are intended to be used by trained medical personnel in a clinic or hospital environment.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042133